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(54) Balloon compressor for internal fixation of bone fractures

(57) The present invention is directed toward a method and apparatus for performing an internal fixation of fractures of tubular bones using a balloon catheter fixation device (10) which is guided and transported through the medullary canal (42) and fracture site (41) of the bone by one or more guide wires (13,15) mounted in said balloon catheter fixation device (10). A bone cement is preferably applied to the fracture site (41) and the balloon catheter (16) is inflated inside the bone and tightened by applying pressure on the catheter (14) outside of the bone by tightening the catheter tube (14) and holding the same in plane in an inflated condition to apply a compression force across the fracture site (41) enhancing the stability of the fractured bone and promoting osseous healing.

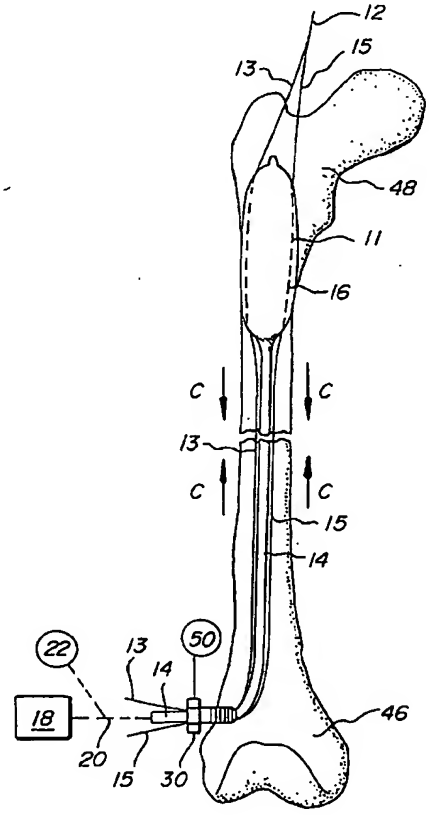

Fig. 2

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is generally directed toward an apparatus for the internal fixation of fractures of tubular bones by compression.

2. Brief Description of the Background

Currently, fractured tubular bones are transfixed surgically by either metal plates and screws or intramedullary metal rods.

It is known that with internal fixation of fractures with plate and screw devices it is desirable to apply a compressive force across the fracture site. Bone is a viscoelastic material and support of the structure and transmission of load is the mechanical function of bone. Bone is strongest in compression and weakest in tension. When a compressive force is applied across a fracture site it allows the fractured segments of bone to be placed in close proximity and the compressive force stimulates the bone in healing. If compression is applied at the fracture site, the intimate contact of the bone fragments restores the structural stability of the bone and allows the direct transfer of force from fragment to fragment rather than only through the implant. A compressive force applied directly at the fracture site hastens the healing of bone by encouraging the formation of new osteons which bridge the fracture line promoting a primary type of bone healing.

Some bone fracture realignment procedures involve insertion of a wire into the medullary canal which is then guided through the bone segments often in conjunction with a partially inserted nail for leverage. When the segments are aligned, the nail is fully inserted and the wire is withdrawn.

Metal intramedullary devices, which function as internal splints, have been used for many years to align fractures of tubular bones. These devices may take the form nails, United States Patent Number 5,034,013; tubular members, United States Patent Number 4,467,794; or a multiple pin device, United States Patent Number 4,457,301. A steerable intramedullary fracture reduction device having an elongated shaft with a steerable tip pivotally mounted to the distal end of the shaft is shown by United States Patent Number 5,002,543. In this patent, a tip actuating apparatus near the proximal end of the shaft enables the operator to steer the tip and the shaft into successive segments of the fractured bone, even when the segments are transversely or rotationally displaced so that the segment can be aligned by the shaft. Metal compression devices which are used for fractures are shown by United States Patent Numbers 4,275,717; 4,227,518; 3,779,239 and 3,760,802. The aforenoted metal compression devices are generally directed towards a threaded rod which is inserted within the medullary canal of a fractured tubular bone. The rod is provided with a distal end having an expandable spreadable sheath or fingers which expand upon rotation of the rod. The proximal end of the rod is located outside of the bone and is provided with a nut which holds the rod in place inside the bone thereby causing the fractured bone portions to be held together. United States Patent Number 4,946,459 shows an intramedullary device for fixing and extending separated portions of a long bone within the body of a patient. The device has a tubular sleeve which is nailed to one end of the bone and an adjustment assembly with a moveable member which bears against an end of the nail. The moveable member can be moved from outside the patient to adjust the separation between the portions of the fractured bone.

The aforementioned prior art devices have metal fingers or sleeves which engage the walls of the medullary canal of the bone with deleterious effects.

The use of such prior art intramedullary devices involves the reaming of the medullary cavity which has the effect of destroying the inner lining of blood vessels. Furthermore the ends of long bones in children are also the growth center of the bones. Drilling or gouging through the ends causes damage and may stop or deform further growth.

Other prior art devices currently use dynamic compression plates and screw devices to apply compression across the fracture site. However, for insertion of this type of device, it is necessary to make a large surgical incision over the outer cortex of the bone directly at the fracture site. Placing this type of fixation device entails the disturbance of the soft tissues overlying the fracture site, disturbance of the fracture hematoma, and stripping the periosteium of bone which compromises the blood supply to the bone at the fracture site.

A flexible bladder device has been described by United States Patent Number 4,313,434 to align fractures intramedullarly. However, this bladder device is designed to be placed directly at the fracture site to provide fixation. The bladder device was not designed for compression at the fracture site and when inflated at the fracture site actually promotes separation of the fracture fragments and has the opposite effect of the present balloon catheter compression device.

There is no known intramedullary device currently available that applies a compressive force at the fracture site in addition to aligning the fracture.

SUMMARY OF THE INVENTION

An improved method and apparatus for treatment of fractures of tubular bones relies on the principle of compressive force to align fractures of tubular bones and to promote and hasten the healing of such fractures. The intramedullary balloon of the balloon catheter is designed to be guided and transported through the medullary canal of the bone and placed either proximal or distal to the fracture site. The balloon when inflated

with sterile saline solution is held securely in place in the medullary canal of the bone acting as an intramedullary anchor for the balloon catheter. It is the elastic property of the catheter that when tightened against the rigid immobile force of the anchoring balloon allows the fractured segments of the bone to align and come in intimate contact. With further tightening of the catheter a compressive force is applied across the fracture sight.

It is an object of the invention to provide a fracture compression device which minimizes damage to the interior blood vessels and periosteium of the bone and in some embodiments allows the guide wire to be removed.

Preferably a bioabsorbable bone cement is used in combination with the compressive force to set the fracture site.

More preferably a quick hardening biomaterial such as Norian SRS is used in combination with the compressive force to set the fracture site.

In the accompanying drawings, there is shown an illustrative embodiment of the invention from which these and other objectives, novel features and advantages will be readily apparent.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross sectional schematic of the invention showing insertion of the inventive balloon catheter device into the bone;

Figure 2 is a cross sectional schematic of the invention showing fixation of the balloon catheter in the medullary canal of the bone and compressive tightening of the fractured portions of the bone with the sensing and fluid transmission elements shown in block diagram;

Figure 3 is a cross section of the inflated balloon with a fluted outer wall; and

Figure 4 is a cross section schematic of the fixation post with balloon catheter extending therethrough.

DETAILED DESCRIPTION OF THE INVENTION

A preferred embodiment and best mode of the invention is shown in Figures 1 and 2. The intramedullary balloon compression device 10 is used to treat fractures of tubular bones by applying intramedullary compression at the fracture site.

When a tubular bone 40 is fractured at a fracture site 41, the catheter device 10 can be inserted into the medullary canal 42 of the bone through a small incision either proximal or distal to the site of the fracture via a catheter introducer. A small aperture 44 is made in the outer cortex of the bone portion 46 with an introducing bone drill and drill bit or bone awl to access the medullary canal of the bone. Once the aperture 44 is created in the bone, the balloon catheter device 10 with lead wire 12 and double guide wires 13 and 15 or additional guide wires if such are needed is inserted into the medullar cavity of the bone by a catheter introducer 60. The balloon compression device 10 is preferably constructed of a plastic extruded material such as polyethylene, teflon, kevlar or other durable material is then guided by the guide wires 13 and 15 past the fracture site 41 into the other portion 48 of the fractured bone. The balloon catheter device 10 is formed with a plurality of lumens 11 along its length for guide wire insertion. Location of the lumens 11 are shown in phantom in Figure 2. The guide wires may be removable from the balloon catheter or permanently incorporated in the catheter. The balloon 16 of the catheter device is inflated to its maximum diameter via the elastic catheter tube 14 with sterile saline solution by means of a syringe 18, associated feed tube 20 and a balloon pressure gauge monitor 22 as shown by respective block diagrams. It is envisioned that the shape of the balloon 16 can be modified in various forms, including smooth, fluted as shown in Figure 3 or ridged outer walls for promoting endosteal blood supply at the site of the balloon insertion. The inflated balloon 16 is held securely in place by the positive pressure applied to the intramedullary walls of the bone. Once the balloon 16 is anchored in place past the fracture site 41, the attached catheter tube 14 can be tightened.

If desired a bone-mineral substitute, bone cement or bioabsorbable bone cement can be applied to the fractured bone ends prior to application of the compression force. One suitable bone-mineral substitute is a calcium phosphate compound with a sodium phosphate solution. Monocalcium phosphate, monohydrate, tricalcium phosphate and calcium carbonate are dry mixed and a sodium phosphate solution is added to form a paste which is malleable and hardens in about 10 minutes. After implantation the paste hardens and turns into carbonated apatite.

The catheter tensioning device is provided with a calibrated force measuring device such as a strain gauge 50 to measure the compression force. The tightening of the catheter 14 with the fixed balloon 16 in place aligns the fracture and compresses the proximal and distal portions 46 and 48 of the fractured bone together. After alignment and compression of the fracture with the intramedullary balloon compression catheter, the catheter 14 is secured firmly to the bone 46 at it's insertion site 44 with a screw, post or peg type of fixation device 30. Thus, the balloon compression catheter can be incorporated into existing bone fixation technology such as an intramedullary rod, a fixation screw or plate, hip screw or total joint arthroplasty that uses a balloon catheter to enhance fixation to the bone. Preferably, the post 30 is hollow with a head 32 and stem 33 which is exteriorly threaded at 34. The stem 33 defines a throughgoing bore 35 with leads into lumen 31 and opens into an arcuate ball seat 36 which is cut into the lumen wall. The bore 35 is threaded to receive a fixation screw 37 which is used to tighten a crimping ball 38 to crimp the catheter tube 14 within the fixation port. The crimping ball 38 can be instructed of metal or plastic. The catheter tube 14 extending through the lumen 31 of

the post is thus clamped or affixed to the bone fixation post. The fixation post 30 and catheter 14 can be respectively released and tightened, if necessary, to apply further compression at the fracture site.

In operation, the fixation post, which may be smooth and possibly threaded, fits into the aperture that was cut in the bone for insertion of the balloon catheter. The catheter is inserted through the hollow center of the head 33 and lumen 31 of the shaft portion of the fixation post. After the catheter is guided past the fracture site in the medullary canal of the bone by guide wires, the balloon portion of the catheter is inflated away from the fracture site and in doing so does not compromise the extramedullary periosteal blood supply or the intramedullary blood supply at the fracture site. The compression force of the catheter allows the fractured fragments of bone to be aligned in close apposition promoting healing of the fracture similar to the prior art dynamic compression plate device without making an incision at the fracture site and without compromising the blood supply at the fracture site. The device does not disturb the fracture hematoma which is essential for healing of the fracture. A tensioning device fits over the head 33 of the fixation post. At this stage bone cement or bone-mineral substitute can be applied. The balloon catheter is then tightened with the tensioning device. This reduces the fracture distance, applying compression at the fracture site. After the bone is aligned and compressed at the fracture site, the crimping ball 38, which lies in a separate tunnel or bore 35 within the shaft of the fixation post is tightened with the threaded set screw 37. When tightened against the tube of the catheter, the crimping ball 38 occludes the central lumen of the catheter tube 14 keeping the balloon 16 inflated thus securing the catheter within the shaft of the fixation post.

After the fracture is healed, or alternatively in some cases after the bone cement has set up, the set screw can be released, the balloon deflated and the catheter and fixation post can be easily removed from the bone. If necessary, additional balloon catheters can be similarly positioned in place for fixation. The balloon compression catheter can be used independently for the intramedullary compression fixation of tubular bones or can be used as a supplement with bioabsorbable bone cement or to metal intramedullary devices to apply compression across the fracture site.

The intramedullary balloon compression catheter is designed specifically to apply a compressive force at the fracture site, to align the fractured bone and promote healing of the fracture.

Osteogenesis is promoted by compression across a fracture site and the intramedullary balloon compression catheter facilitates this in an intramedullary fashion.

In the foregoing description, the invention has been described with reference to a particular preferred embodiment, although it is to be understood that specific details shown are merely illustrative, and the invention may be carried out in other ways without departing from the true spirit and scope of the following claims:

Claims

1. An assembly for setting a fractured bone comprising a balloon catheter (10) with tubing (14), said balloon catheter defining an inflation section (16) which inflates when said balloon catheter (10) is pressurized and at least one throughgoing lumen (11), a guide wire (13,15) mounted in said lumen (11), said inflation section (16) being inflated in a first fractured bone portion (48) to fixedly engage said bone segment and anchor means (30) mounted in another fractured bone portion (46) distal from said first fractured bone portion (48), said anchor means (30) being secured to said catheter tubing (14) to hold said balloon catheter (10) in a tensioned condition which provides compression on the fracture site (41) of fractured bone portions (46,48).

2. An assembly for setting fractured bones comprising a balloon catheter (10) with a tubing (14) having an inner lumen and an inflatable balloon (16) with fluted sides secured to said tubing (14) at the distal end thereof, said balloon (16) with fluted sides being in fluid communication with the lumen of said tubing, a guide wire (13,15) mounted to said balloon (16) and means (30) separate from said balloon catheter (10) adapted to be mounted in a portion (46) of said fractured bone distal from said balloon with fluted sides (16) to receive said tubing (14) and hold said balloon catheter (10) when said balloon with fluted sides (16) is inflated in a fixed stressed condition to provide compression on the fracture site of fractured bone portions (46,48).

3. An assembly for setting fractured bones comprising a balloon catheter (10) with a tubing (14) having an inner lumen and an inflatable balloon (16) secured to said tubing (16) at the distal end thereof, said balloon (16) being in fluid communication with the lumen of said tubing (14), a guide wire (13,15) mounted to said balloon (16) and means (30) separate from said balloon catheter (10) adapted to be mounted in a portion (46) of said fractured bone distal from said balloon (16) to receive said tubing (14) and hold said balloon catheter (10) when said balloon (16) is inflated in a fixed stressed condition to provide compression on the fracture side of fractured bone portions (46,48) and a fluid discharge means (18) connected to said balloon catheter (10) and communicating with said tubing lumen to allow fluid discharge from said fluid discharge means (18) into said tubing lumen to inflate the balloon (16) of said balloon catheter (10).

4. An assembly as claimed in claim 3, wherein said means (30) adapted to be mounted in a portion of said fractured bone is a hollow post member (30) with external screw threads (34) and includes set

screw means (35,36,37,38) moveably mounted therein.

5. An assembly as claimed in claim 4, wherein said set screw means (37) comprises a ball seat (36) defined by said hollow post (30), a throughgoing channel (35) formed in said hollow post member (30) leading into said ball seat (36), a ball (38) seated in said ball seat (36) and a set screw (37) moveably mounted in said throughgoing channel (35) adapted to engage and move said ball (38).

6. An assembly as claimed in any one of the preceding claims, including a pressure monitoring means (50) connected to said balloon catheter (10) to measure the pressure of the inflated balloon (16) of said balloon catheter (10).

7. An assembly as claimed in any one of the preceding claims, wherein said catheter tubing (14) is flexible and reinforced.

8. An assembly for setting a fractured bone by holding the fractured bone portions (46,48) together under a compression force across the fracture site (41) comprising a balloon catheter (10) with a tubing (14) having an inner lumen and an inflatable balloon (10) secured to said tubing (14) and being in fluid communication with the lumen of said tubing (14), said balloon catheter (10) being sized to move within the medullary cavity of the bone, a guide wire (13,15) mounted to said balloon (16) and mounting means (30) adapted to be mounted in a portion (46) of said fractured bone distal from said balloon (16), said mounting means (30) selectively engaging said tubing (14) and holding said tubing (14) in a fixed stressed condition to provide compression on the fracture site (41) of fractured bone portions (46,48) after said balloon (10) has been inflated inside one of said bone portions, and means (18) connected to said tubing allowing the inflation of said balloon with fluid.

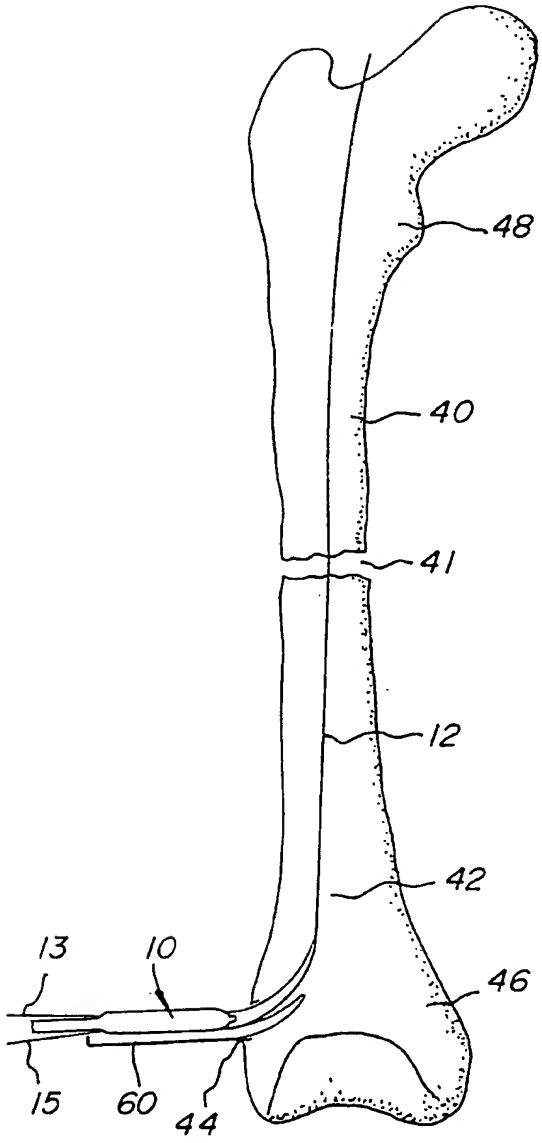
9. An assembly as claimed in claim 8, wherein said mounting means comprises a post member (30) with a throughgoing lumen (31) and set screw means (35,36,37,38) threadably mounted to said post member (30) and extending into said lumen (31).

10. An assembly as claimed in claim 9, wherein said set screw means (35,36,37,38) comprises a ball seat (36) defined by said post member (30) communicating with said lumen (31), a throughgoing channel (35) cut in said post member (30) leading into said ball seat (36), a ball (38) seated in said ball seat (36) and extending into said lumen (31) and a set screw (37) moveably mounted in said throughgoing channel (35) adapted to engage and move said ball (38) into said lumen (31).

11. A method of setting a fractured bone by compression comprising the steps of:

a) cutting an aperture (44) into one portion (46) of the fractured bone away from the site of the fracture (41) allowing communication with the medullary canal (42) of the bone;
b) inserting a balloon catheter device (10) through the aperture (44) cut in the bone into the medullar cavity (42) of the bone;
c) guiding the balloon catheter device (10) Past the fracture site (41) into another portion (48) of the fractured bone;
d) inflating the balloon (16) of the balloon catheter device (10) to its maximum diameter so that the balloon catheter device (10) is held securely in place by the positive pressure of the balloon (16) applied to the intramedullary walls of the bone; and
e) tightening the attached catheter (14) with the fixed balloon (10) in place to align the fracture and compress the proximal and distal portions (46,48) of the fracture bone together.

Fig. 1



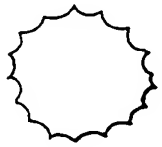


Fig. 3

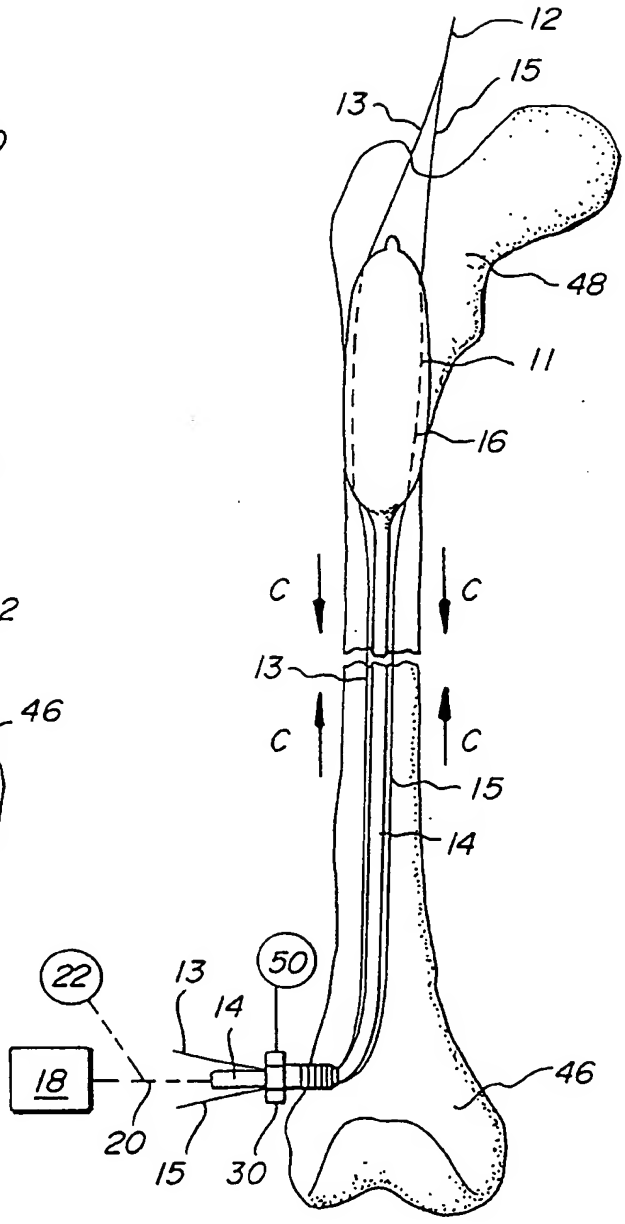


Fig. 2

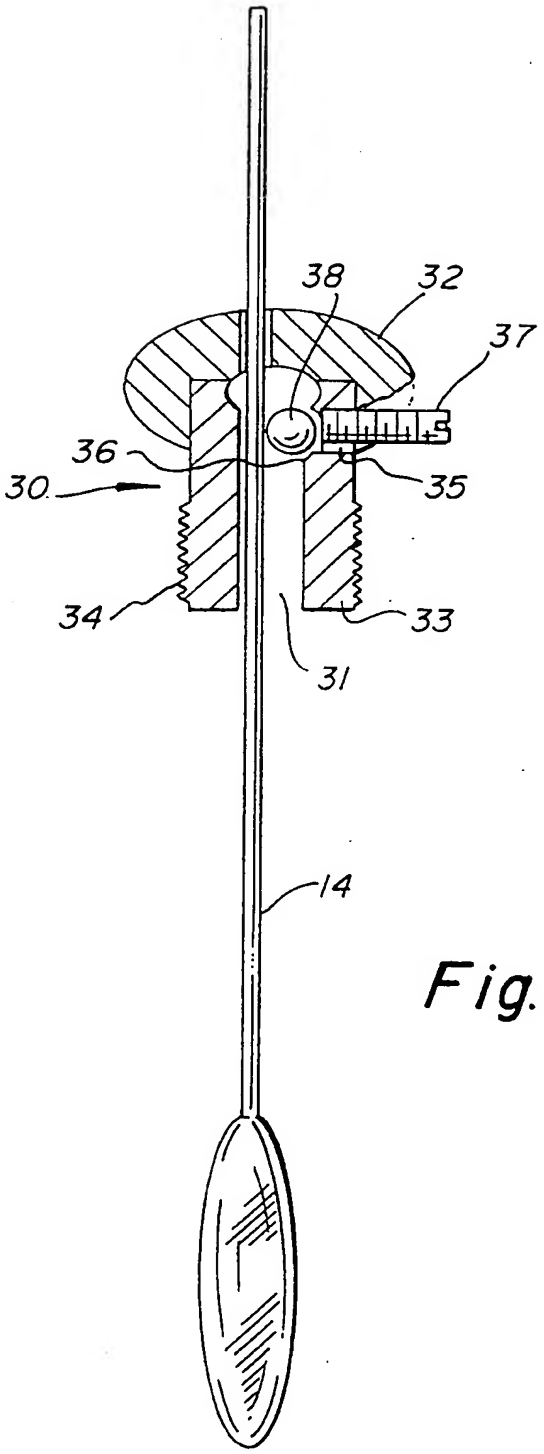


Fig. 4

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 95 30 4043

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US-A-4 313 434 (SEGAL) * figure 2 *	1-3,8	A61B17/72 A61B17/00
A	US-A-5 102 413 (PODDAR) * abstract; figure 2 *	1-3,8	
A	US-A-5 263 931 (ADVANCED CARDIOVASCULAR) * figure 1 *	1	
A	US-A-5 104 399 (ENDOVASCULAR TECHNOLOGIES) * figure 7 *	2,3,8	
A	DE-C-824 377 (POHL) * figure 9 *	1-3,8	
A	WO-A-91 10407 (HARDY)		
A	DE-A-39 24 610 (GEORGES)		
A	DE-A-33 47 333 (MECRON)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
THE HAGUE	30 October 1995	Barton, S

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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EP 95 30 4043

-C-

INCOMPLETE SEARCH

Claim not searched: 11

Method for treatment of the human or animal body by surgery or therapy (see article 52(4) of the European Patent Convention)